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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/410,368	09/30/1999	JOHN R. HAVENS	244/006	6760

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EXAMINER

MARSCHER, ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant N .

09/410,368

Examiner

Ardin Marschel

Applicant(s)

HAVENS ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,21-26,28-39 and 67-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19,21-26,28-39 and 67-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 21.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other:

DETAILED ACTION

Applicants' amendment, filed 5/6/03, has been approved for entry and has been entered. Due to the newly applied rejections, summarized below, the finality of the office action, mailed 2/6/03, is hereby withdrawn.

Applicants' arguments, filed 5/6/03, have been fully considered and they are deemed to be persuasive to overcome the previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 6, 19, 26, and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Reconsideration of the written basis for the instant claim limitations directed to acidic or basic pH conditions caused by the application of an electronic potential at at least one electrode as set forth in claim 6 reveals that this is NEW MATTER. It is firstly noted that claim 6, as originally filed, cites the providing of a pH change as a result of an electronically generated potential of an electrode and not that acidic or basic conditions is thereby produced. Consideration of the remainder of the instant application as filed has also failed to reveal written basis for the electronic potential providing either acidic

or basic conditions. The altering of pH conditions overlaying the array is described on page 22, lines 11-12, but not that acidic or basic conditions are achieved. A specific low pH or acidic hydrolysis of acetal groups is described on page 10, lines 15-18, of the specification but that this specific practice does not supply written basis for generic pH change via electronic potential for acidic or basic conditions. Thus, the above listed claims contain NEW MATTER.

VAGUENESS AND INDEFINITENESS

Claims 1-13, 15-19, 22-26, 29-39, and 67-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 6, cites the phrase "the microarray" which lacks antecedent basis as to such a microarray. There is no previously cited microarray to refer to by said phrase in the claim previous to the referring phrase "the microarray" in said line 6 of claim 1. Similarly, claims 2-13, 67-71, and 87 cite a microarray of claims 1 etc. but confusingly it is not clear whether the above cited microarray in claim 1 is meant as an entity separate from the bulk of the claim 1 microchip device limitations or whether the wording is actually meant to direct claim 2 to a limitation of the microchip device of line 1 of claim 1 without utilizing a clear reference thereto. It is noted that claim 14 does not cite a microarray per se. Claims 15-19, 72-80, and 88, however, directly or indirectly cite a microarray in their respective lines 1 therein but without these microarray citations clearly corresponding to the microchip device of claim 14 or some other microarray. Similarly, claim 21 lacks any microarray limitation, however, claims 22-26, 81-86, and

89 do cite a microarray in their first lines without clear antecedent basis. Similarly, claim 28 lacks any microarray limitation, however, claims 29-39 do cite a microarray in their first lines without clear antecedent basis. Clarification via clearer claim wording is requested.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 7-16, 21-24, 67, 69, 72, 73, 75, 81, 82, 84, and 87-89 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Heller et al. (P/N 5,632,957).

Upon reconsideration Heller et al. discloses a microchip device, as summarized in the abstract, which contains microlocations on which reactions, such as nucleic acid hybridization reactions or antibody/antigen reactions, may be controlled in a microscopic format. The device is disclosed as being utilized for nucleic acid hybridization at the microlocations thereon also in column 4, line 48, through column 5, line 17, via binding entities, such as nucleic acids. A device is depicted in Figure 14 with details described in column 17, line 22, through column 18, line 50. An electrode (item 190) is disclosed

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which is shown in said Figure 14 to be overlaid with a plug of material as described in column 17, lines 27-37, which thus captures a permeation layer. The permeation layer (column 17, line 38, through column 18, line 4) is made up of material, such as acrylamide (instant claims 87-89) including an attached DNA capture probe attached as disclosed in column 18, lines 5-10. Each lysine group of a poly-L-lysine polymer is a polymerizable moiety, instantly claimed as moiety "P" in instant claim 1 with a covalent bond (Schiff base reaction product), instantly moiety "X" (instant claim 13 covalent bond as well as an amide, ketone, and carbonyl), to which is attached a DNA capture probe (via an oxidized ribonucleoside which is an activation as required in instant claim 24), instantly moiety "R". The lysine groups of the poly-L-lysine are attached in a polymeric molecule which anticipates the bonding of moiety "P" groups of instant claim 1 to other "P" moieties. It is noted that instant claims 2, 72, and 81 include allyl as well as homoallyl moieties for "P" which is reasonably interpreted as including lysines, as in the reference, which each contain an allyl moiety segment. The poly-L-lysine is thus part of the permeation layer and therefore results in a covalent attachment within the permeation layer matrix as required in instant claims 14 and 21. The DNA capture probes are utilized for capture, via hybridization of derivatized biomolecules as described regarding the "R" moiety in instant claim 1, in the reference in that target or reporter DNA is disclosed in column 19, lines 15-42, as being derivatized for fluorescence detection or other derivatizations such as radioactivity, thus indicating that the DNA capture probe clearly anticipates the "R" moiety limitations of the instant invention. It is noted that the DNA capture probe contains amines in nucleobases which

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is an amine moiety R group as required in instant claims 3,15, 22, 69, 75, and 84. The lysines of the poly-L-lysine are amine moieties, "P", as containing amine as well as a amide in their structure as required in instant claims 67, 73, and 82. Instant claims 7-11 are anticipated in that the covalent structure of the poly-L-lysine attached to the DNA capture probe results in all the "R" and "P" groups being attached to each other as required in various limitations in instant claims 7-11. Poly-L-lysine as the P moieties are the same as all being lysines as required in instant claims 12, 16, and 23.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-18, 21-24, 28-34, 38, 67, 69, 72, 73, 75, 81, 82, 84, and 87-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (P/N 5,632,957); taken in view of Meade et al. (P/N 5,770,369).

Heller et al. has been summarized above as disclosing the basics of the instant invention but lacks specific disclosure of an activation step prior to participating in a binding reaction to a derivatized biomolecule as required in instant claims 4, 5, and 28

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under acidic or basic conditions. Heller et al., however, does motivate and suggest that hybridization between a nucleic acid, or DNA, capture probe and a target nucleic acid occurs in order to bind a derivatized nucleic acid, or biomolecule onto the R moieties of the reference and as instantly claimed.

Meade et al. is a description of hybridization practice between nucleic acids which may be detected via electron flow to an electrode on which a nucleic probe has been attached as is similar subject matter to that of Heller et al. Description of said hybridization practice is set forth in Meade et al. in column 8, line 47, through column 11, line 33. In column 11, lines 34-40, Meade et al. describes a variety of hybridization conditions utilized for said hybridization practice. The practice of utilizing specific hybridization conditions is deemed an activation prior to binding occurring as required in instant claims 4, 17, and 28 via treatment with buffer components. An example of such hybridization/activation conditions which are utilized in a hybridization reaction is set forth in Meade et al. at column 34, lines 18-29, wherein slightly basic conditions are utilized at pH = 7.2 as also a claim limitation in instant claims 5 and 18.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the Meade et al. hybridization conditions for such reactions as performed in Heller et al. to result in the particular instant claim embodiments directed to activation of the DNA capture probe of Heller et al. in order to result in binding to a derivatized biomolecule or target nucleic acid therefore resulting in the practice of these embodiments of the instant invention which are claimed in the above listed rejected claims. Regarding instant claim 17 the hybridization of a target to

a probe nucleic acid is broadly a polymerization reaction as a polymeric, that is, nucleic acid duplex, is made as a result and thus instant claim 17 is also rejected hereinunder. It is noted that there is no specific limitation as to what type of polymerization is being limited to in instant claim 17. Instant claim 18 is also rejected due to said polymerization occurring in slightly basic conditions as pointed to above. The permeation layer (Heller et al. at column 17, line 38, through column 18, line 4) is made up of material, such as acrylamide as also required in instant claim 29.

Claims 1-5, 7-18, 21-25, 28-34, 38, 67, 69, 72, 73, 75, 81, 82, 84, and 87-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (P/N 5,632,957); taken in view of Meade et al. (P/N 5,770,369); taken further in view of Dorner et al. (P/N 6,121,489).

The above combination of Heller et al.; taken in view of Meade et al. has been summarized above but does not describe the activation of instant claim 25 directed to acidic or basic conditions for the bonding reaction between moieties "P" and "R" as instantly claimed. The bonding between "P" and "R" in Heller et al. is performed as noted in column 18, lines 5-10, therein as being via a Schiff base reaction.

Dorner et al. describes the conditions for a Schiff base reaction in column 28, lines 37-42, as being performed under mildly acidic conditions.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform the bonding of nucleic acid to lysine in a Schiff base reaction as suggested and motivated in Heller et al. under acidic conditions thus resulting in the invention of instantly claimed embodiments as in instant claim 25.

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No claim is allowed.

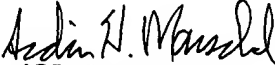
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 21, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER